DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 10,1997

Ms. Cynthia Pearson
Executive Director
National Women's Health Network
514 10th Street, NW
Suite 400
Washington, D.C. 20004

Re: Docket No. 88P-0431/CP

Dear Ms. Pearson:

This letter responds to your December 14, 1988 petition to the Food and Drug Administration (FDA) concerning the regulatory status of the "Micro-Condom" developed by SFT Laboratories, Inc. (formerly Anthl Laboratories, Inc.), the "Barrier" female condom developed by the Energy Basin Clinic, and the "Femshield" (WPC 333) device developed by the Wisconsin Pharmacal Company.

You requested that FDA rescind its 510(k) "approval," halt distribution and require premarket approval of the above devices and "hold hearings" on how these "new" contraceptive devices were marketed through the 510(k) process. Subsequent to your petition, the names of the "Barrier" and "Femshield" devices were changed to "Bikini" female condom and "Reality" female condom, respectively.

We apologize for the long delay in our formal response. However, as you know, FDA has addressed all of the devices listed in your petition. The regulatory status of these devices is as follows:

- FDA has classified "Micro-Condom" type devices into class III as glans sheaths (59 Fed. Reg. 67185; December 29, 1994) and plans to initiate rulemaking, as priorities allow, under section 515(b) of the Federal Food, Drug and Cosmetic Act (act) to require premarket approval applications (PMAs). In the interim, the "Micro-Condom" may be marketed, with specific labeling restrictions, under a 510(k) submission (i.e., substantial equivalence determination).

- The "Barrier/Bikini" female condom, may not be legally marketed in commercial distribution without the submission of a new 510(k) premarket notification demonstrating the device's substantial equivalence to a legally marketed device more appropriate than the Class II condom (21 CFR 884.5300)

- The "Femshield/Reality" female condom, has FDA PMA approval. FDA has made available (55 FR 23299; June 7, 1990) draft guidelines for clinical data for premarket approval of "new" female barrier contraceptives such as the "Bikini" and "Reality" female condoms and, as priorities allow, will classify such female condoms into class III and propose 515(b) rulemaking to require PMA submissions.

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Thus, following procedures specified in the act and implementing regulations, FDA has taken a number of actions that address your petition (see enclosed addendum for more particulars) and, as priorities and the statute allow, will take further necessary actions. To this degree, then, your petition is granted. If you have any questions about this petition response, please contact Joseph M. Sheehan at (301) 827-2974.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

Enclosure

Addendum- Response to Citizen Petition
Submitted by National Women's Health Network

Requirements of the Act and Regulations

Section 513 of the act (21 U.S.C. 360c) requires FDA to classify medical devices in commercial distribution before May 28, 1976, into one of the three categories: class I (General Controls), class II (Special Controls), and class III (Premarket Approval). Under section 513(f) of the act (21 U.S.C. 360c(f)), any "new" (i.e. postamendments) device intended for initial commercial distribution after May 28, 1976, is in class III and requires premarket approval unless FDA determines that the "new" device is substantially equivalent to: a device marketed commercially before May 28, 1976, that is classified into class I or class II; a device marketed after that date that has been reclassified into class I or class II; or a device classified into class III for which the Agency has not issued an order requiring premarket approval under section 515(b) of the act. If FDA determines that a "new" device is substantially equivalent to such a predicate device, it is in the same class as the predicate device to which it is substantially equivalent and may be commercially marketed without premarket approval.

Under section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807, after the submission to the Agency of a premarket notification (510(k) notification) and the Agency's issuance of an order finding the "new" device substantially equivalent to a legally marketed predicate device, the "new" device may be introduced into interstate commerce for commercial distribution under the same regulatory scheme as the predicate device. However, a determination of substantial equivalence does not constitute Agency approval of the safety and effectiveness of the device. A finding of substantial equivalence does not preclude FDA from classifying either the predicate or the "new" device into class III under section 513 of the act.

"Micro-Condom" Device

On August 19, 1988, following its review of Anthl Laboratories' 510(k) notification, FDA found that the "Micro-Condom", which is a latex cap covering the glans (head) of the penis, was substantially equivalent to devices that were commercially distributed for contraceptive purposes before May 28, 1976. The Agency required the manufacturer to specify in labeling that the device is intended only for preventing pregnancy and not for preventing the transmission of sexually transmitted diseases (STDs), such as Acquired Immune Deficiency Syndrome (AIDS).

Subsequently, on March 7, 1989, FDA's advisory Obstetrics-Gynecology Devices Panel (the Panel) met to review the available information on short condom-like devices. The Panel concluded that, because of different performance characteristics, such devices constitute a generic type of device different from conventional full-sheath condoms and recommended that the device category encompassing short condom-like devices be named the glans cap. In agreeing with the Panel, FDA concluded that its original finding that the "Micro-Condom" was substantially equivalent was

incorrect, and so notified the manufacturer. Thus, although short condom-like devices were marketed before the Medical Device Amendments of 1976, these devices (and substantially equivalent post-1976 devices like the "Micro-Condom") had not yet been classified in a regulation: they are not encompassed by the classification regulation (21 CFR 884.5300) for conventional full-sheath condoms. They fall within the generic type of device initially identified as a glans cap and subsequently classified into class III as a glans sheath (21 CFR 884.5320), as discussed below.

In its review of glans cap information, the Panel found no published safety and effectiveness studies and insufficient evidence to establish a performance standard. Because breakage, leakage or dislodgement of such devices, with release of semen, could lead to unwanted pregnancy or transmitted diseases, such as AIDS, because such devices could cause systemic or local tissue reactions when in contact with the penis or vaginal mucosa, and because safety and effectiveness depends on the reliability of the devices to remain in place during use,. e.g. during vigorous intercourse, the Panel recommended that FDA classify the generic glans cap into class III.

FDA agreed with the Panel's recommendations and, after changing the name from glans cap to glans sheath, it published a final rule in the Federal Register of December 29, 1994 (59 FR 67185) (copy attached) to classify the glans sheath device into class III. Under the classification procedures in the act and implementing regulations (see 21 CFR 884.3), commercial distribution of glans sheath devices may legally continue, until the Agency calls for PMA's under section 515(b) of the act, so no action to halt distribution warrants consideration at this time. Nevertheless, FDA has advised SFT Laboratories of the proposed classification of its glans sheath device into class III and of the need to describe in labeling the "data or information upon which the (pregnancy prevention) claim is made" and to explain that no pregnancy prevention rate has been established for the device by controlled clinical studies. Failure to substantiate claims may result in the device being considered adulterated and misbranded.

You requested various actions relating to the "Micro-Condom's" premarket notification (510(k)) "approval". As stated above, FDA has published a final rule to classify the glans sheath (including the "Micro-Condom") into class III and, as priorities allow, will initiate rulemaking under section 515(b) of the act to require PMAs.

"Barrier/Bikini" and "Femshield/Reality" Female Condoms

In August 1987, following its review of the Energy Basin Clinic's 510(k) notification, FDA initially found the "Barrier/Bikini" female condom to be substantially equivalent to the male-use full-sheath condom device. However, following the March 7, 1989 deliberations of the Agency's advisory Panel and its recommendations that, based on new information, pouch-like contraceptives for insertion by females into the vagina should be classified into class III as a generic type of intravaginal pouch that is different than the male-use condom, FDA reversed its earlier decision in April 1989. Similarly, the Agency found that the 510(k) notification for the "Femshield/Reality" intravaginal pouch did not establish the product's substantial equivalence to devices in commercial distribution before May 28, 1976. Thus, within months of receipt of your petition, FDA notified the manufacturers of both

devices that approval of a PMA is required to begin commercial distribution because the two devices are "new" devices and in class III by virtue of section 513(f) of the act. Thus, issues you have raised concerning the appropriateness of 510(k)s for the "Barrier/Bikini" female condom and the "Femshield/Reality" devices are now moot.

As you are aware, on August 25, 1989, at an open meeting of the Panel, FDA provided the public with the opportunity to discuss draft guidelines FDA developed describing the type of clinical trial data that would be required to obtain premarket approval of female barrier devices (e.g. the "Barrier/Bikini" and "Femshield/Reality" devices) intended to prevent transmission of STDs, including AIDS. FDA announced the availability of these guidelines in the June 7, 1990 Federal Register (55 FR 23299). These matters were further discussed at open sessions of the Agency's advisory Panel held on January 31, 1992 and December 10, 1992, in conjunction with the Panel's and FDA's review of the PMA for the "Femshield/Reality" intravaginal pouch, later called the "Reality" female condom. Thus, your concerns about female barrier contraceptive devices have been aired publicly, by you and others, at four open sessions of the Panel held in 1989 and 1992.

As you know, on May 7, 1993, FDA approved a PMA for the "Reality" female condom. Though the "Barrier/Bikini" intravaginal pouch is classified in class III by statute (as mentioned above), FDA is further prepared, in concurrence with its Panel's March 7, 1989 classification recommendations and as agency priorities allow, to publish a proposed rule to classify such devices into class III under the generic name "female condom", rather than "intravaginal pouch", as a category of devices that is distinct from the class II male condom. Upon final classification, FDA will initiate 515(b) rulemaking to require PMA approval for any female condoms marketed before the 1976 Amendments and any post-1976 substantially equivalent female condom devices.